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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,484

03/16/2006

Yoshinori Kosugi

20078.0027USWO

7353

52835

7590

11/24/2008

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MINNEAPOLIS, MN 55402-0902

EXAMINER

VENCI, DAVID J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

11/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,484	Applicant(s) KOSUGI ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 25, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 15-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Unity of Invention

Examiner acknowledges Applicants' elections, without traverse, in Applicants' reply filed August 25, 2008.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. New restriction is required under 35 U.S.C. 121 and 372 and necessitated by applicant's amendments adding new claims 15-29.

- I. Claims 1 and 15-22, drawn to a method comprising an antibody recognizing HRF.
- II. Claim 28, drawn to a method comprising an antibody recognizing HRF.
- III. Claim 23-26, drawn to a kit comprising an antibody recognizing HRF.
- IV. Claim 27 and 29, drawn to drugs comprising an antibody recognizing HRF.

According to PCT Rules 13.1 and 13.2, inventions must form a single general inventive concept by sharing a common technical feature that contributes over the prior art. However, Inventions I through IV do not form such a single general inventive concept because the technical feature common to Inventions I through IV does not contribute over the prior art.

Specifically, the antibody recognizing HRF, which is a component of the compositions and kit of Invention III and IV, and is used in the methods of Inventions I and II. However, Sanchez *et al.*, 18 ELECTROPHORESIS 150 (1997), describes antibodies recognizing HRF (see Section 2.3 Antibody production and immunoblot analysis).

Therefore, unity of invention is lacking because Inventions I through IV do not form a single general inventive concept by sharing a common technical feature that contributes over the prior art. In accordance with 37 CFR 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

Art Unit: 1641

This application contains claims directed to the following patentably distinct species:

1. Select ONE method from:

- a. sample contact with support-immobilized antibody; OR (claim 15)
- b. sample fixed and sectioned. (claim 16)

2. Select ONE antibody "source" from:

- a. mammal vaccinated with "a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 90 to 130 of SEQ ID NO:2" immunogen; (claims 17, 20, 26, 27)
- b. mammal vaccinated with "a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 1 to 95 of SEQ ID NO:2" immunogen; OR (claims 18, 21, 26, 27)
- c. mammal vaccinated with "a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 115 to 172 of SEQ ID NO:2" immunogen. (claims 19, 22, 26, 27)

Applicants are required to elect ONE method from species group 1, and ONE antibody "source" from species group 2, *supra*. Examination on the merits shall be restricted to Applicants' elected species so long as generic claims 1, 23 or 27-29 are under rejection. Upon allowance of a generic claim, Applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of the allowable generic claim as provided by 37 CFR 1.141.

The method species lack unity of invention because they do not form a single general inventive concept under PCT Rule 13.1 and lack the same special technical feature under PCT Rule 13.2 by virtue of requiring different reagents, different sample processing steps, different data analysis and different diagnostic endpoints. The antibody species lack unity of invention because they do not form a single general inventive concept under PCT Rule 13.1 and lack the same special technical feature under PCT Rule 13.2 by virtue of having been sourced from mammals vaccinated with different immunogens.

Art Unit: 1641

Applicant is advised that a complete reply to this requirement must include: (i) elections of both a species and invention to be examined, even if the requirement is traversed¹ (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention and species. An argument that claims are allowable or that all claims are generic is considered non-responsive unless accompanied by a complete election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication should be directed to David Venci whose telephone number is (571)272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

/dv/

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641

¹ Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect *with traverse*. Should Applicant traverse on the ground that the inventions or species are not patentably distinct from each other, Applicant should clearly admit on the record, or submit or identify evidence already on the record that the inventions or species are obvious variants over each other. However, if Examiner finds one Invention or species unpatentable over prior art, Examiner may use the evidence or admission of record to reject other inventions or species under 35 U.S.C.103(a). If Applicant elects *with traverse* but does not distinctly and specifically point out supposed errors in this restriction requirement, then Applicant's election is considered incomplete and treated as an election *without traverse* pursuant to MPEP § 818.03(a). Failure to timely argue in support of traversal will result in the loss of right to petition under 37 CFR 1.144.